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Olson et al.

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(54) **REDUCED PRESSURE WOUND DRESSING HAVING A WOUND CONTACT SURFACE WITH COLUMNAR PROTRUSIONS**

(75) Inventors: **Jonathan S. Olson**, Austin, TX (US); **Devin C. Ginther**, Dripping Springs, TX (US); **T. Blane Sanders**, San Antonio, TX (US)

(73) Assignee: **KCI Licensing, Inc.**, San Antonio, TX (US)

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CPC A61F 13/00068; A61F 2013/00089; A61F 2013/00217; A61F 2013/00331; A61F 2013/00519; A61F 2013/0054
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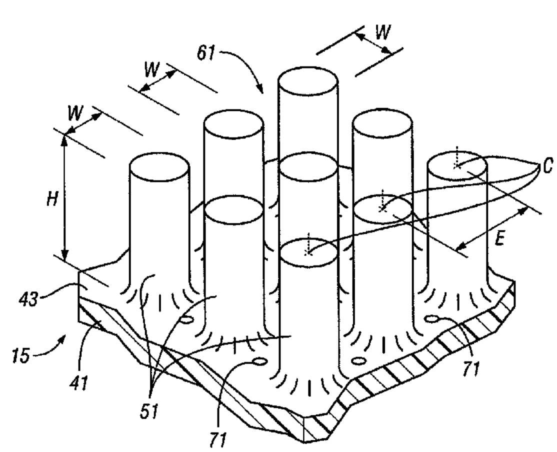
Primary Examiner — Leslie Deak
Assistant Examiner — Kai Weng

(57) **ABSTRACT**

A reduced pressure treatment system includes a distribution manifold having a backing substrate with a first side and a second side and a plurality of protrusions positioned on the first side of the backing substrate. Each of the protrusions includes a substantially circular cross-sectional shape and has a diameter of between about 0.1 and 2.0 millimeters, the backing substrate having a plurality of apertures formed therein to allow fluid communication between the first side and the second side opposite the first side. A reduced pressure source is fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to a tissue site.

17 Claims, 4 Drawing Sheets



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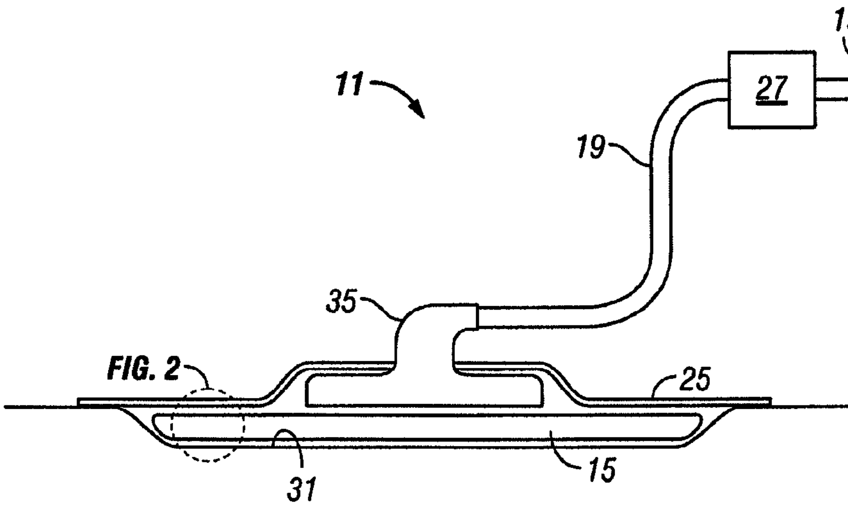

FIG. 1

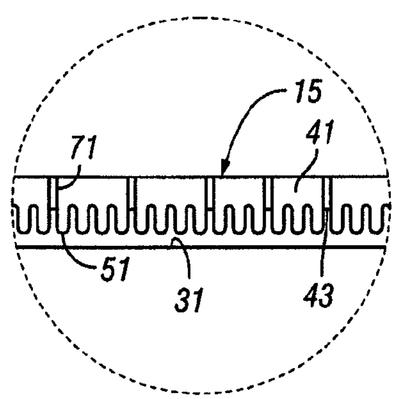

FIG. 2

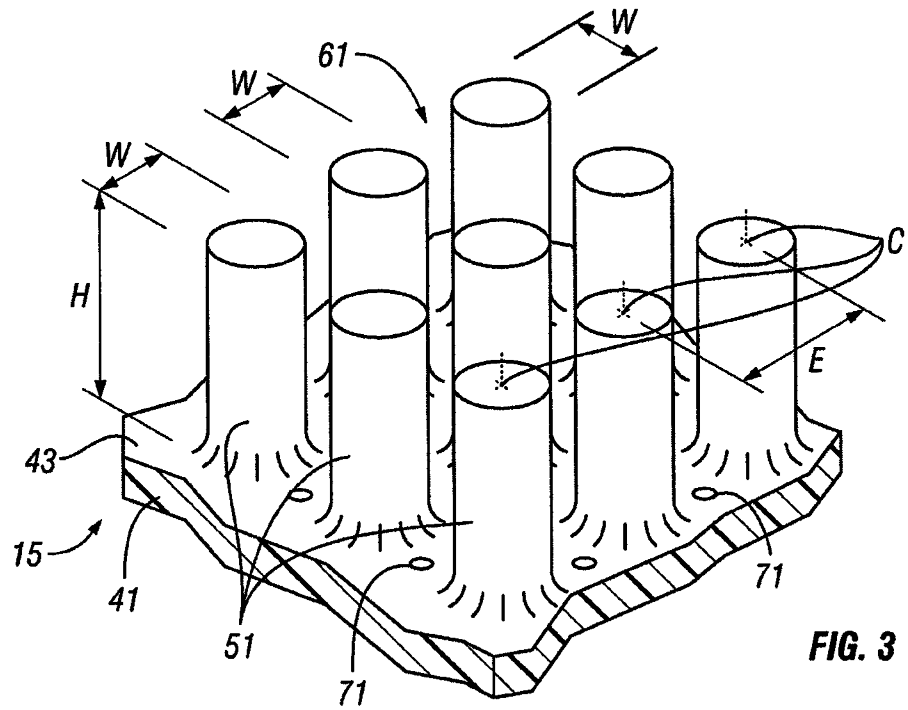

FIG. 3

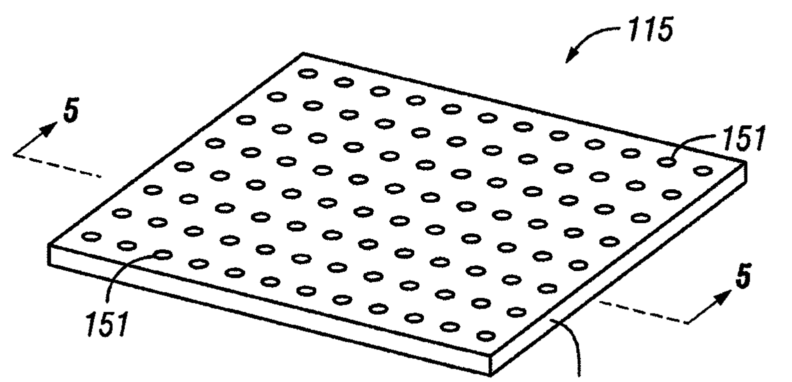

FIG. 4

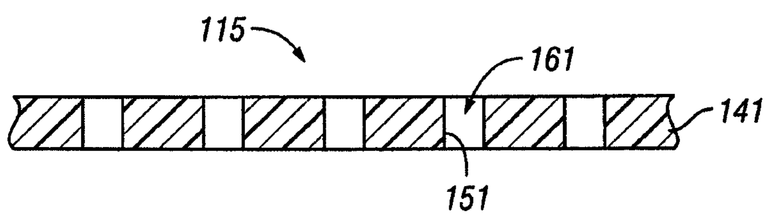

FIG. 5

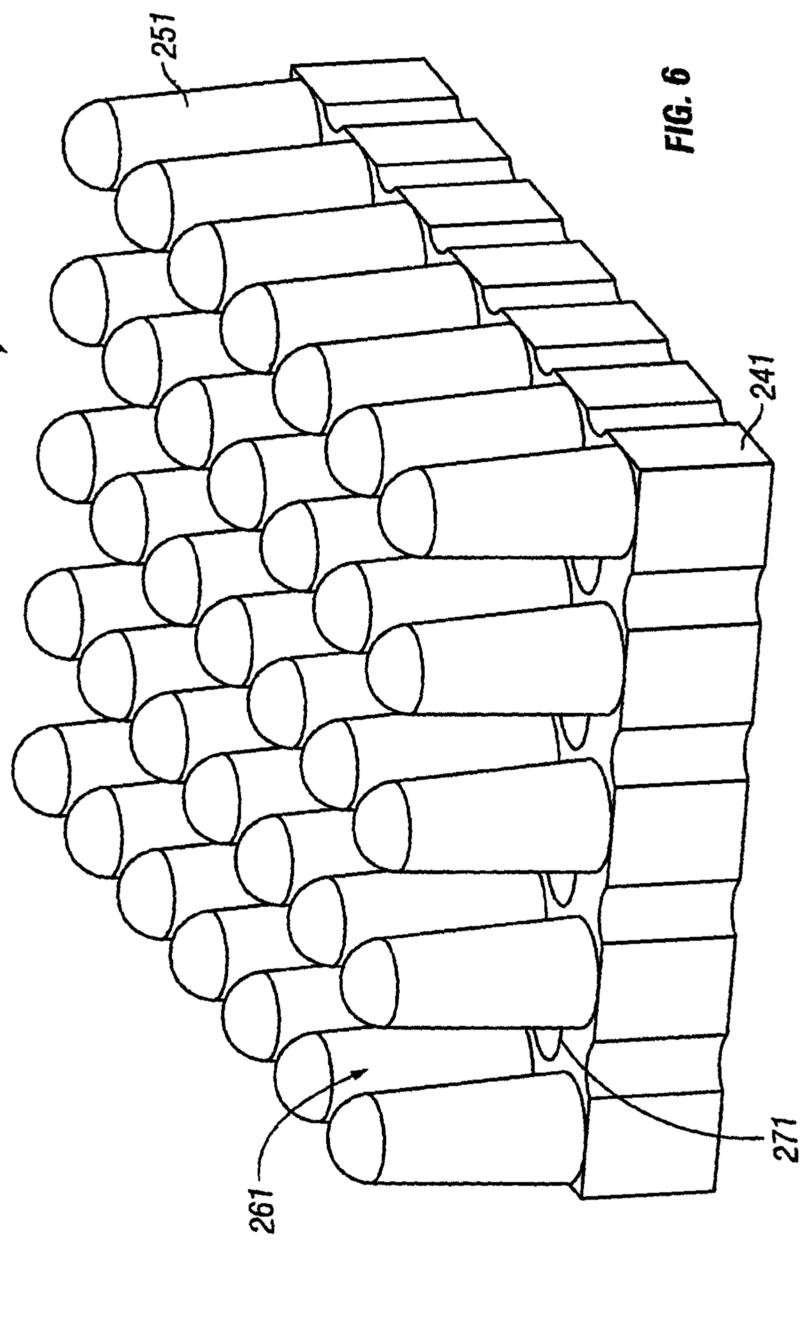

FIG. 6

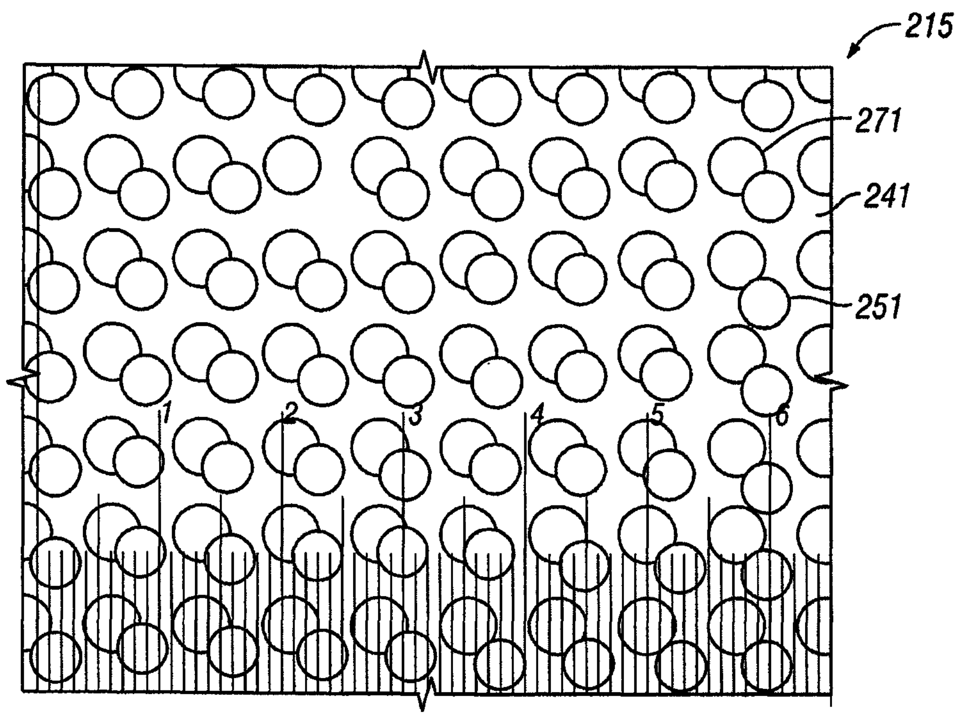

FIG. 7

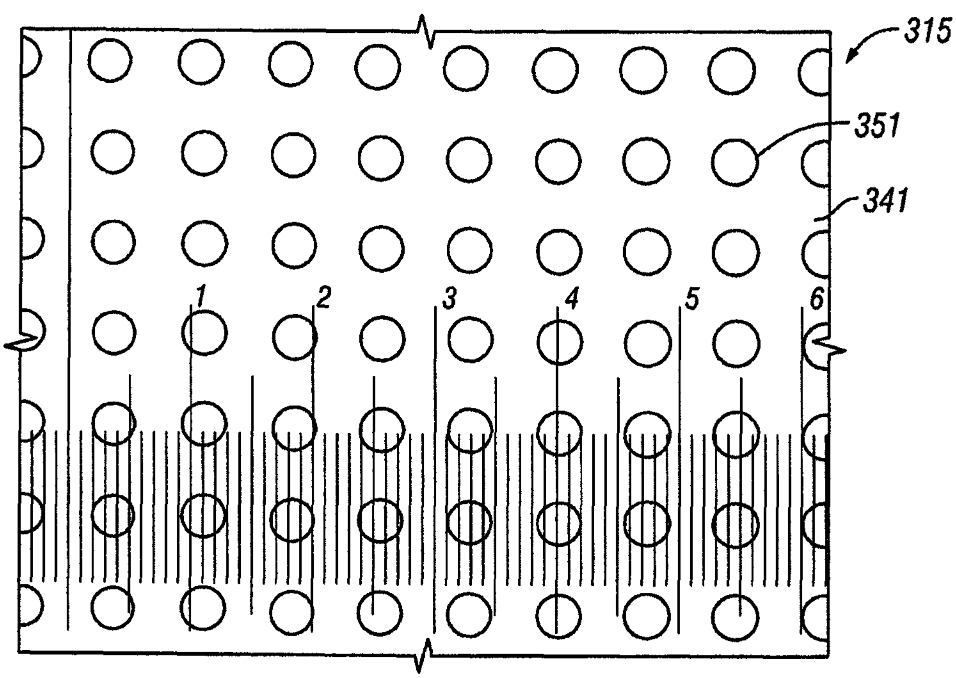

FIG. 8

REDUCED PRESSURE WOUND DRESSING HAVING A WOUND CONTACT SURFACE WITH COLUMNAR PROTRUSIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/118,524, filed May 9, 2008 now U.S. Pat. No. 8,057,447, which claims the benefit of U.S. Provisional Application No. 60/928,644, filed May 10, 2007, both of which are hereby incorporated by reference.

BACKGROUND

1. Field of the Invention

The present invention relates generally to tissue treatment systems and in particular to distribution manifolds for wound treatment.

2. Description of Related Art

Clinical studies and practice have shown that providing a reduced pressure in proximity to a tissue site augments and accelerates the growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but application of reduced pressure has been particularly successful in treating wounds. This treatment (frequently referred to in the medical community as "negative pressure wound therapy," "reduced pressure therapy," or "vacuum therapy") provides a number of benefits, including faster healing and increased formulation of granulation tissue. Typically, reduced pressure is applied to tissue through a porous pad or other manifolding device. The porous pad contains cells or pores that are capable of distributing reduced pressure to the tissue and channeling fluids that are drawn from the tissue. The porous pad often is incorporated into a dressing having other components that facilitate treatment.

Distribution manifolds for delivering reduced pressure treatment are also commonly referred to as reduced pressure dressings, or in the case of treatment of a wound, wound dressings. Such dressings are characterized by structural features that allow fluid flow through the material. For example, one material that is often used as a wound dressing is reticulated, open-cell polyurethane foam. The foam includes a plurality of interconnected pores that allow fluid flow throughout the foam. When a reduced pressure is applied to one area of the foam, this reduced pressure is quickly distributed to other areas of the foam and is easily transmitted to tissues adjacent the foam. One problem with open-cell foams and similar materials is tissue in-growth, which prevents easy removal of the foam following treatment. For open cells foams with pore sizes on the order of 100-1000 microns, in-growth of tissue may occur relatively quickly. As the new tissue enters the pores or cells of the foam, the foam acts as a lattice, and tissue grows within the pores and around the walls that form the perimeter of the pores. This effectively attaches the foam to the tissue site, and the foam must be forcibly removed by tearing the new tissue and breaking any bonds that have formed between the tissue and the foam. Not only is this detrimental to the healing process, but the tearing of this tissue may cause discomfort to the patient.

One way to circumvent the problem of tissue in-growth is to increase the frequency of dressing changes. If new dressings are applied with increased frequency, there is less tissue in-growth, and thus less disruption of new tissue upon removing the old dressing. One downside to increased dressing changes is the increased costs associated with materials (i.e. new dressings) and labor. Changing a dressing is labor intensive and diverts the attention of medical personnel from other important tasks. Increased dressing changes also result in more aggravation to patients and their wounds.

SUMMARY

The problems presented by existing reduced pressure treatment systems are solved by the systems and methods of the illustrative embodiments described herein. In one embodiment, a reduced pressure treatment system is provided and includes a distribution manifold including a backing substrate and a plurality of protrusions positioned on a first side of the backing substrate with each of the protrusions having substantially circular cross-sectional shape and having a diameter of between about 0.1 and 2.0 millimeters. The backing substrate has a plurality of apertures formed therein to allow fluid communication between the first side and a second side opposite the first side. A reduced pressure source fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to a tissue site.

In another embodiment, a reduced pressure treatment system is provided and includes a distribution manifold including a backing substrate and a plurality of protrusions positioned on a first side of the backing substrate, each of the protrusions having a substantially polygonal cross-sectional shape and having a width of between about 0.1 and 2.0 millimeters. The backing substrate has a plurality of apertures formed therein to allow fluid communication between the first side and a second side opposite the first side. A reduced pressure source fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to a tissue site.

In another embodiment, a reduced pressure treatment system is provided and includes a distribution manifold including a backing substrate and a plurality of columnar voids positioned on a first side of the backing substrate, each of the columnar voids having substantially polygonal cross-sectional shape and having a width of between about 0.1 and 2.0 millimeters.

In another embodiment, a reduced pressure treatment system is provided and includes a distribution manifold including a backing substrate and a plurality of protrusions positioned on a first side of the backing substrate, each of the protrusions having substantially circular cross-sectional shape and tapering inward from the base at which the protrusions meet the backing substrate. The backing substrate has a plurality of apertures formed therein to allow fluid communication between the first side and a second side opposite the first side. A reduced pressure source is fluidly connected to the apertures of the backing substrate to deliver the reduced pressure through the apertures, between the protrusions, and to a tissue site.

Other objects, features, and advantages of the illustrative embodiments will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a reduced pressure treatment system **11** according to an embodiment of the present invention.

FIG. **2** illustrates the distribution manifold according to an embodiment of the present invention.

FIG. **3** illustrates the shape of the protrusions of the distribution manifold according to an embodiment of the present invention.

FIG. **4** illustrates a plurality of columnar voids of a distribution manifold according to an embodiment of the present invention.

FIG. **5** illustrates a plurality of columnar voids of a distribution manifold according to an embodiment of the present invention.

FIG. **6** illustrates a backing substrate with circular protrusions according to an embodiment of the present invention.

FIG. **7** represents an illustrated reproduction of a photograph of a distribution manifold taken through a microscope according to an embodiment of the present invention.

FIG. **8** represents an illustrated reproduction of a photograph of an exemplar distribution manifold having a plurality of columnar voids disposed in a backing substrate according to an embodiment of the present invention.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

In the following detailed description of the illustrative embodiments, reference is made to the accompanying drawings that form a part hereof. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is understood that other embodiments may be utilized and that logical structural, mechanical, electrical, and chemical changes may be made without departing from the spirit or scope of the invention. To avoid detail not necessary to enable those skilled in the art to practice the embodiments described herein, the description may omit certain information known to those skilled in the art. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the illustrative embodiments are defined only by the appended claims.

The several embodiments of the present invention described herein are provided to assist in the healing of wounds and generation of new tissue. Reduced pressure therapy is administered to patients with a reduced pressure delivery system. This form of advanced wound healing therapy can be readily integrated into a clinician's wound healing procedures. The therapy optimizes patient care and decreases costs associated with treatment of patients having traumatic and chronic wounds. With the innovative embodiments of the reduced pressure delivery system described herein, reduced pressure therapy can be administered either in the hospital, in community settings such as assisted living complexes and convalescence homes, or in the home.

Reduced pressure delivery to a wound or tissue site promotes wound healing and/or tissue growth by removing infectious materials and other fluids from the wound or tissue site. Reduced pressure treatment further promotes tissue growth by imposing forces on the tissue, thereby causing micro-deformation of the tissue, which is believed to contribute to the development of granulation tissue at the tissue site. The forces imposed on the tissue site by the delivery of reduced pressure further encourage improved blood flow to the tissue site, which further assists in the growth of new tissue.

Referring to FIG. **1**, a reduced pressure treatment system **11** according to an embodiment of the present invention includes a reduced pressure dressing, or distribution manifold **15** fluidly connected to a reduced pressure conduit **19**. The reduced pressure conduit **19** is fluidly connected to a reduced pressure source **23** such as a vacuum pump or another source of suction. The distribution manifold **15** is placed against a tissue site **31** of a patient and is used to distribute a reduced pressure provided by the reduced pressure source **23**. Typically, reduced pressure is maintained at the tissue site by placing an impermeable or semi-permeable cover **25** over the distribution manifold **15** and the tissue site **31**. The reduced pressure also serves to draw wound exudates and other fluids from the tissue site **31**. A canister **27** may be fluidly connected to the reduced pressure conduit **19** and disposed between the wound dressing **15** and the reduced pressure source **23** to collect the fluids drawn from the tissue site **31**. A distribution adapter **35** may be connected to the reduced pressure conduit **19** and positioned on the distribution manifold **15** to aid in distributing the reduced pressure to the distribution manifold **15**.

Referring to FIGS. **2** and **3**, the distribution manifold **15** is particularly well suited to promote tissue growth at the tissue site **31** yet prevent in-growth of new tissue into the distribution manifold **15**. The distribution manifold **15** includes a backing substrate **41** with a tissue contact surface **43**. The tissue contact surface **43** preferably includes a plurality of projections, or protrusions **51** that extend from the backing substrate **41**. As more specifically shown in FIG. **3**, the shape of the protrusions **51** may be substantially cylindrical in shape. Alternatively, the cross-sectional shape of the protrusions **51** may be square, rectangular, triangular, polygonal, elliptical, or any other shape. The protrusions **51** may be tapered or of uniform cross-sectional area throughout.

Referring more specifically to FIG. **3**, the height, H, of the protrusions **51** is preferably between about 0.1 and 5.0 millimeters, and more preferably about 2 millimeters. The width, W, of each protrusion is between about 0.1 and 2.0 millimeters, and more preferably about 0.25 to 0.5 millimeters. The width of the protrusions **51** illustrated in FIG. **3** equals that of the diameter since the cross-sectional shape of each protrusion **51** is circular. If the protrusions **51** are square in cross-sectional shape, the width of the protrusions **51** are an edge length of the square. For other cross-sectional shapes, the width is the average of the longest lateral distance through the centroid, C, of the cross section and the shortest lateral distance through the centroid of the cross section. The lateral, center-to-center spacing, E, between each protrusion **51** is preferably between about 0.1 and 1.0 millimeters, and more preferably about 0.5 millimeters. The spacing of the protrusions **51** create distribution channels **61** through which reduced pressure may be delivered to the tissue site **31** and exudates withdrawn from the tissue site **31**. It is generally preferred that the height of the protrusions **51** be greater than the width of the protrusions **51**. More specifically, the ratio of height to width, H:W, should be greater than about 1:1, and more preferably greater than about 2:1.

The shape, sizing, and spacing of the protrusions **51** may vary depending upon the particular tissue site **31** being treated, the type of material from which the protrusions **51** and backing substrate **41** are made, and the amount of reduced pressure being applied to the tissue site **15**. For example, for tissue sites that are highly exudating, it may be advantageous to position the protrusions farther apart to maintain adequate distribution channels **61** between the protrusions **51**. In one embodiment of the present invention, the shape, sizing and spacing of the protrusions **51** is uniform for a particular distribution manifold **15**. In other embodiments, the shape, sizing, and spacing of the protrusions **51** may vary. For example, protrusions **51** having different cross-sectional shapes may be disposed on the backing substrate **41**. Similarly, the sizing and spacing of the protrusions **51** may vary to supply selected portions of the tissue site **31** with more or less reduced pressure.

The presence and sizing of the protrusions **51** allow the protrusions **51** to distribute reduced pressure to the tissue site **31**, but prevent new tissue that grows at the tissue site **31** from attaching to the protrusions **51** of the distribution manifold **15**. By eliminating the pores or cells that are typically used to deliver reduced pressure to a tissue site, new tissue is not able to wrap around the walls that form the pores or cells. While new tissue growth will grow into the field of protrusions **51** and may even wrap around some of the protrusions **51**, the new tissue is not capable of securing itself to the protrusions **51** since the base of each protrusion is anchored to the backing substrate **41**.

In addition to distributing reduced pressure to the tissue site **31**, the distribution manifold **15** also serves to impart stresses and strains to the tissue site **31** similar to those seen with cellular foam that traditionally has been used in reduced pressure systems. Other materials sometimes used in reduced pressure systems as distribution manifolds, such as gauze, do not have this effect on tissue. The stresses and strains created by the distribution manifold **15** are believed to cause micro-deformation of existing tissue and plays a significant role in the generation of new tissue at the tissue site. The amount of stress and strain imparted to a tissue site is determined by the amount of reduced pressure supplied to the tissue site and the surface morphology of the manifold that contacts the tissue site. As reduced pressure is applied, portions of the tissue site are pulled against the distribution manifold **15**, and more particularly against the protrusions **51**, which results in the development of stresses and strains within the tissue. The sizing of the protrusions **51** on a scale similar to that of the pores of the cellular foam is believed to be one reason for the development of stresses and strains that are similar to those seen with use of the foam.

In one embodiment, the backing substrate **41** is formed from the same material as the protrusions **51**. Preferably, that material is silicone or another medical grade material that is relatively impermeable to fluid flow. Alternatively, the material may be a semi-permeable material that allows select fluids or amounts of fluids to pass. The backing substrate **41** may include a plurality of apertures **71** that allow distribution from a surface of backing substrate **41** opposite the protrusions **51** to the tissue contact surface **43** from which the protrusions **51** extend. Since the presence of the apertures **71** could have the same effect on tissue in-growth as that of pores, it is important that the backing substrate **41** and protrusions **51** be removed from the tissue site **31** prior to any new tissue advancing into the apertures **71**. In practice, this may be accomplished by knowing the approximate rate of tissue growth, the height of the protrusions **51**, and determining the amount of time likely required for new tissue growth to reach the apertures **71**.

While the distribution manifold **15** has primarily been described as including backing substrate **41** and plurality of protrusions **51**, the distribution manifold **15** may further include cellular foam or another material that is positioned adjacent to or attached to the surface of the backing substrate **41** opposite the protrusions **51**. The use of a cellular foam or other material increases the ability of the reduced pressure conduit **19** or the distribution adapter **35** to deliver and distribute reduced pressure to the backing substrate **41**. The protrusions **51** and backing substrate **41** serve as a barrier to new tissue growth entering pores of the cellular foam or other material.

Referring to FIGS. **4** and **5**, a distribution manifold **115** according to another embodiment of the present invention is illustrated. Instead of a plurality of protrusions such as those of distribution manifold **15**, distribution manifold **115** includes a plurality of columnar voids **151** formed or otherwise positioned within a backing substrate **141**. The term columnar is not meant to imply any particular cross-sectional shape, since the shape of the voids may be any shape as described previously with reference to protrusions **51**. Rather, the term columnar refers to the voids generally being greater in length than in width. The voids **151** themselves create a plurality of distribution channels **161** that may be joined by a main channel at an end of the distribution channels **161** opposite that of a tissue site. Alternatively, the distribution channels **161** may simply be apertures that pass completely through the backing substrate **141**.

The shape and size of the voids **151** may be similar to that of the protrusions **51** of manifold **15**. As previously described, a cellular foam, distribution adapter, or other manifolding device may be placed in fluid communication with the distribution channels **161** to deliver reduced pressure to the tissue site.

Exemplary Distribution Manifold Having Protrusions

Referring to FIGS. **6** and **7**, one particular distribution manifold **215** that has been tested and that has demonstrated growth induction rates similar to those of cellular foam utilizes a two inch diameter backing substrate **241**. The backing substrate includes a plurality of protrusions **251** that are generally circular in cross-sectional shape and tapered inward from the base at which the protrusions meet the backing substrate **241**. A plurality of apertures **271** are provided in the backing substrate **241** to allow fluid communication with distribution channels **261** between the protrusions **251**. The apertures **271** are disposed in rows and columns that are positioned between the rows and columns of the protrusions **251**. The positioning of the apertures **271** in this pattern results in one aperture **271** being centered between every four adjacent protrusions **251** that are arranged in a square pattern (see FIG. **6**).

The sizing of the protrusions **215** is such that on the two inch diameter backing substrate **241**, approximately 7500 protrusions are present. The width of each protrusion at the base is about 0.5 mm, the height of each protrusion is about 1.5 mm, and the lateral center-to center spacing between the protrusions is about 0.75 mm. The ratio of height to width of the protrusions is about 3:1, and the ratio of the spacing to width is about 1.5:1. The tapering of each protrusion **51** is about a five degree draft angle from the longitudinal axis of the protrusions **51** to aid in molding the distribution manifold **215**.

Distribution manifold **215** was sized based on an expected rate of tissue growth and the desired period of use between changes of the distribution manifold **215**. For reduced pressures of about 125 mm Hg, one to two millimeters of tissue growth may be expected over a 48 hour period. Since it is desired to change the distribution manifold **215** every 48 hours, a protrusion height of about 1.5 mm allows the majority of the spacing between the protrusions **251** to fill with new tissue growth between dressing changes, but prevents the tissue from attaching to the distribution manifold **251**.

Referring more specifically to FIG. **7**, an illustrated reproduction of a photograph of the distribution manifold **215** taken through a microscope is provided. The photograph illustrates a top view of the distribution manifold **215** showing the protrusions **251** extending from the backing substrate **241**. Also illustrated are apertures **271** disposed between the protrusions **251**.

Exemplary Distribution Manifold Having Voids

Referring to FIG. **8**, an illustrated reproduction of a photograph of an exemplar distribution manifold **315** having a plurality of columnar voids **351** disposed in a backing substrate **341** is provided. The backing substrate **341** is about 1.5 mm thick, and the width (diameter) of each void **351** is about 0.35 mm. Since the voids **351** extend through the backing substrate **341**, the height of each void **351** is about 1.5 mm. The lateral center-to-center spacing between the voids **351** is about 0.75 mm. The ratio of height to width of the voids is about 4.3:1, and the ratio of the spacing to width is about 2.1:1.

It should be apparent from the foregoing that an invention having significant advantages has been provided. While the invention is shown in only a few of its forms, it is not just limited but is susceptible to various changes and modifications without departing from the spirit thereof.

We claim:

1. A reduced pressure treatment system for delivering a reduced pressure to a tissue site comprising:

a distribution manifold including a backing substrate having a first side adapted to face a tissue site, a second side opposite the first side, and a plurality of protrusions extending from the first side of the backing substrate, wherein the plurality of protrusions have a substantially circular cross-sectional shape having a width between about 0.1 and 2.0 millimeters and a height greater than the width, and wherein the backing substrate has a plurality of apertures formed between the first side and the second side to allow fluid communication between the first side and the second side; and

a reduced pressure source adapted to be fluidly connected to the apertures on the second side and configured to deliver reduced pressure through the apertures to the first side between the protrusions and to the tissue site;

whereby the protrusions maintain a specific height to width ratio that prevents new tissue growth from attaching to the distribution manifold.

2. The reduced pressure treatment system of claim **1**, wherein a lateral center-to-center spacing of the protrusions is between about 0.1 and 0.5 millimeters.

3. The reduced pressure treatment system of claim **1**, wherein a ratio of the height to diameter of the protrusions is 2:1.

4. The reduced pressure treatment system of claim **1**, wherein the protrusions are made from medical grade silicone.

5. A reduced pressure treatment system for delivering a reduced pressure to a tissue site comprising:

a distribution manifold including a backing substrate having a first side adapted to face a tissue site, a second side opposite the first side, and a plurality of protrusions extending from the first side of the backing substrate, wherein the plurality of protrusions have a substantially polygonal cross-sectional shape having a width between about 0.1 and 2.0 millimeters and a height greater than the width, and wherein the backing substrate has a plurality of apertures formed between the first side and the second side to allow fluid communication between the first side and the second side; and

a reduced pressure source adapted to be fluidly connected to the apertures on the second side and configured to deliver reduced pressure through the apertures to the first side between the protrusions and to the tissue site;

whereby the protrusions maintain a specific height to width ratio that prevents new tissue growth from attaching to the distribution manifold.

6. The reduced pressure treatment system of claim **5**, wherein a lateral center-to-center spacing of the protrusions is between about 0.1 and 0.5 millimeters.

7. The reduced pressure treatment system of claim **6**, wherein a ratio of the height of the protrusions to the width of the protrusions is 2:1.

8. The reduced pressure treatment system of claim **5**, wherein the protrusions are made from medical grade silicone.

9. A reduced pressure treatment system for delivering a reduced pressure to a tissue site comprising:

a distribution manifold including a backing substrate having a first side adapted to face a tissue site, a second side opposite the first side, and a plurality of columnar voids extending from the first side of the backing substrate, wherein the plurality of columnar voids have a substantially polygonal cross-sectional shape having a width between about 0.1 and 2.0 millimeters and a height greater than the width, and wherein the backing substrate has a plurality of apertures formed between the first side and the second side to allow fluid communication between the first side and the second side; and

a reduced pressure source adapted to be fluidly connected to the apertures on the second side and configured to deliver reduced pressure through the apertures to the first side between the columnar voids and to the tissue site;

whereby the columnar voids maintain a specific height to width ratio that prevents new tissue growth from attaching to the distribution manifold.

10. The reduced pressure treatment system of claim **9**, wherein a height of the columnar voids is about 1.5 mm.

11. The reduced pressure treatment system of claim **9**, wherein the backing substrate is about 1.5 mm thick.

12. The reduced pressure treatment system of claim **9**, wherein the columnar voids completely pass through the backing substrate.

13. The reduced pressure treatment system of claim **9**, wherein a lateral center-to-center spacing between the plurality of columnar voids is about 0.75 mm.

14. The reduced pressure treatment system of claim **9** wherein:

the columnar voids create a plurality of distribution channels that are joined to a main channel at an end of the distribution channels; and

a reduced pressure source is fluidly connected to the distribution channels of the backing substrate to deliver the reduced pressure to the tissue site.

15. The reduced pressure treatment system of claim **14**, further comprising a cellular foam positioned adjacent to the plurality of distribution channels.

16. The reduced pressure treatment system of claim **9**, wherein the plurality of columnar voids are square, rectangular, triangular, polygonal, or elliptical shaped.

17. The reduced pressure treatment system of claim **9**, wherein the plurality of columnar voids are tapered.

* * * * *